IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re United States Patent Application of:		**Docket No.:**	**4240-149**
Applicants:	**PARK, Yoon Jeong, et al.**	**Conf. No.:**	**7380**
Application No.:	**10/593,430**	**Art Unit:**	**1646**
Date Filed:	**September 19, 2006**	**Examiner:**	**Elizabeth C. Kemmerer, Ph.D.**
Title:	**BONE GRAFT AND SCAFFOLDING MATERIALS IMMOBILIZED WITH OSTEOGENESIS ENHANCING PEPTIDES ON THE SURFACE**	**Customer No.:**	**23448**

CERTIFICATE OF EFS FILING

I hereby certify that this document is being filed via EFS in the United States Patent and Trademark Office on **October 9, 2008**.
/kelly k. reynolds/

RESPONSE TO JULY 9, 2008 RESTRICTION REQUIREMENT AND PETITION FOR EXTENSION OF TIME IN U.S. PATENT APPLICATION NO. 10/593,430

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

Sir:

This responds to the July 9, 2008 Office Action in the above-identified application. The time for responding to the July 9, 2008 Office Action without extension was set at one month or August 9, 2008. Applicants hereby request a two month extension of time under 37 C.F.R. § 1.136 to extend the deadline for response to October 9, 2008. This Response is therefore timely.

In response to applicant's response filed May 21, 2007, the examiner has withdrawn the previous Restriction Requirement. By the July 9, 2008 Office Action, a Requirement for Election was made, requiring species election in each of the following categories:

Part I:	Cell adhesion-inducing peptide and/or tissue growth factor-derived peptide;
Part II:	Bone graft material; and
Part III:	Crosslinkers.

In response, Applicants elect, with traverse, a single member of each of Parts I, II and III, as set forth in detail below.

Part I – Cell Adhesion-inducing peptide and/or tissue growth factor-derived peptide

Applicants are required to select "one of the proteins recited in claim 4 or 13, or a specific combination thereof." While the examiner identifies the class as containing "cell adhesion-inducing peptides" and/or "tissue growth factor-derived peptides," claims 4 and 13 contain only recitations of tissue growth factor-derived peptides. It is respectfully submitted that the cell adhesion-inducing peptides should not be included in this classification.

In response, applicants elect, with traverse, the amino acid sequence at positions 16-34 of BMP-2 (SEQ ID NO: 6) as a single peptide of Part I, as recited in claims 4 and 13.

All of the pending claims are readable upon the elected species, as claims 4 and 13 are dependent on generic claims 1 and 10 and no pending claims further restrict those independent claims by reciting subject matter exclusive of the subject matter of claims 4 and 13.

Part II – Bone Graft Material

Applicants are required to select one of the bone graft materials listed in claim 7 or 16. In response, applicants elect, with traverse, organism-derived bone mineral powders as a single bone graft material of Part II, as recited in claims 7 and 16.

All of the pending claims are readable upon the elected species, as claims 7 and 16 are dependent on generic claims 1 and 10 and no pending claims further restrict those independent claims by reciting subject matter exclusive of the subject matter of claims 7 and 16.

Part III - Crosslinkers

Applicants are required to select one of the crosslinkers listed in claim 9 or 22. In response, applicants elect, with traverse, sulfo-SMCC as a crosslinker of Part III.

All of the pending claims are readable upon the elected species, as claims 9 and 22 are indirectly dependent on generic claims 1 and 10 and no pending claims further restrict those independent claims by reciting subject matter exclusive of the subject matter of claims 9 and 22.

Traversal of Species Election Requirement

The requirement for a species election is traversed. The requirement for species election is based on the allegation that the species do not possess unity of invention, as defined under PCT Rule 13.1. The examiner's attention is respectfully directed to MPEP § 1850, PCT Rule 13.2 which states:

> "[w]here a group of inventions is claimed in one and the same international application, the requirement of unity of invention referred to in Rule 13.1 shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features. The expression 'special technical features' shall mean those **technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art**." (emphasis added)

The restriction is traversed under Rule 13.2 as there exist common special technical features which define the contribution the claimed species of Parts I-III make over the prior art. It is submitted that each of the three categories of species identified in the Requirement for Election mailed July 9, 2008 include species that possess common special technical features and therefore possess unity of invention.

Specifically, all members of the group identified as Part I by the examiner are tissue growth factor-derived peptides, described in the specification as "a peptide identified and chemically synthesized from the active site of the tissue growth factor." (Specification, p. 4.) All of these peptides function to achieve a tissue regeneration effect for tissue engineering applications. Effectiveness of materials prepared using such peptides is shown in Test Examples 1-4 of the present application. As such the class provides a technical relationship.

The examiner alleges that this group does not provide a contribution over the prior art, specifically in view of Puleo et al., *Biomaterials*, (2002) 23:2079-2087 (hereinafter Puleo et al.). Applicants respectfully disagree.

The peptides listed in claims 4 and 13 are peptides derived from tissue growth factors. Specifically with respect to BMP-4, the claims recite peptides portions of the full length BMP-4, at amino acid positions 2-18 (SEQ ID NO: 4), 74-93 (SEQ ID NO: 13), 293-313 (SEQ ID NO: 14), 360-379 (SEQ ID NO: 15), and 382-402 (SEQ ID NO: 16). These peptides were specifically identified by the inventors of the present application by their activity.

Puleo et al, however, provides immobilization of a full length BMP-4 on the surface of plasma-treated Ti-6Al-4V. "Compared to studies with peptides, few reports regarding chemically immobilized growth factors are available." (Puleo, p. 2079, col. 2, para. 1.) The studies of Puleo et al. are specifically contrasted to RGD and non-RGD containing peptides (Puleo, p. 2079, col. 1, para. 1.) As such, the peptides of the claims are novel in view of Puleo et al. and therefore the claimed tissue growth factor-derived peptides provide a contribution over the prior art.

The class of tissue growth factor-derived peptides listed in claims 4 and 13 possess a general inventive concept of having been identified as effective in tissue regeneration for tissue engineering applications. Additionally, such general inventive concept provides a special technical feature over the prior art, in particular Puleo et al.

Additionally, all members of the group identified as Part II by the examiner are bone graft materials effective in providing a basis for immobilization of the cell adhesion-inducing peptide and/or tissue growth factor-derived peptide. As such the class provides a technical relationship.

Furthermore, all members of the group identified as Part III by the examiner are crosslinkers effective in immobilizing the surface of the bone graft material. As such the class provides a technical relationship.

In order that this response fairly meets the substance of the Office Action in all respects, even though the election requirement is traversed by Applicants, a single disclosed species of each identified group is hereby elected, subject to the foregoing traversal. It is understood that in a species election, if any species is found to be allowable, that an additional species will be examined, until all species have been examined, *i.e.* all tissue growth factor-derived peptides, all bone graft materials and all crosslinkers. If any generic claim is finally held to be allowable, all claims drawn to species containing all elements of the generic claim will also generally be held to be allowable. (MPEP § 806.04(d)).

CONCLUSION

In response to the Requirement for Restriction dated July 9, 2008, Applicants have provisionally elected, with traverse, the amino acid sequence at positions 16-34 of BMP-2 (SEQ ID NO: 6) as a single peptide of Part I, the organism-derived bone mineral powders as a single bone graft material of Part II and sulfo-SMCC as a crosslinker of Part III.

The examiner correspondingly is requested to reconsider the election requirements in light of the foregoing remarks.

The time for responding to the July 9, 2008 Office Action without extension was set at one month or August 9, 2008. Applicants hereby request a two month extension of time under 37 CFR § 1.136 to extend the deadline for response to and including October 9, 2008. Payment of the extension fee of $245.00 specified in 37 C.F.R. § 1.17(a)(2), as applicable to small entity, is being paid by on-line credit card payment at the time of EFS submission of this Response. Should any additional fees be required or an overpayment of fees made, please debit or credit our Deposit Account No. 08-3284, as necessary.

If any additional issues remain, the Examiner is requested to contact the undersigned attorneys at (919)419-9350 to discuss same, in order that the prosecution of this application is expedited.

Respectfully submitted,

Date: October 9, 2008

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